TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
25974 WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/013879	07.12.2004	10.12.2003

International Patent Classification (IPC) or national classification and IPC

C12Q1/70, G01 N33/53

Applicant

GREINER BIO-ONE GMBH

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 18 sheets, as follows:
      - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

   _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013879

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-58,61-73 as originally filed/furnished

pages* 59,60 received by this Authority on 30.09.2005 with letter of 20.09.2005

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-57 received by this Authority on 30.09.2005 with letter of 20.09.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1/5-5/5 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 29-45 and 53-57 insofar as they relate to SEQ ID Nos. 8-18, 20-31, 42, 43, 45-47 and 83-116

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 29-45 and 53-57

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted the claims nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

   See Supplemental Box.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. **29-45 and 53-57 insofar as they relate to SEQ ID Nos. 19, 32, 41, 44, 48, 82 and 117-135**

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	29-45, 53-57	YES
	Claims		NO
Inventive step (IS)	Claims	29-45, 53-57	YES
	Claims		NO
Industrial applicability (IA)	Claims	29-45, 53-57	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

See Supplemental Box.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

The sequence listing in the description, pages 1-20, as originally filed.

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Boxes III, IV and V

1. The application relates to primers and probes for detecting HPV genotypes.

2. Box IV - Lack of unity of invention (PCT Rule 13)

Various primers and primer combinations for detecting papilloma viruses are known from the cited prior art. The present application also describes various primers; for those with SEQ ID Nos. 1 to 6 the consensus sequence according to claim 1 can be regarded as a compulsory structural feature (PCT Rule 13.2). SEQ ID No. 7 can be regarded as related because a pair of primers is needed in order to carry out the diagnostic method.

The sequences with SEQ ID Nos. 19, 32, 41, 44, 48, 84 and 117 to 135 are not structurally related to the aforementioned sequences. It is already known that the E1 region is preserved and is therefore suitable for HPV diagnosis, and therefore any inventions based on these SEQ IDs are separate inventions (PCT Rule 13). Since no search fees have been paid for these 25 additional inventions, no comment can be made on them. The applicant has identified another invention in the claims, namely "arrays containing probes from the E1 region" (see the original claims 40 to 56) and has paid an additional fee for this. With the Demand for an International Preliminary Examination the applicant submitted a new set of claims and a letter asking for the International Preliminary Examination to be carried

out in respect of the subject matter of the new claims 29 to 45 and 53 to 57 (arrays).

3. Box III - Non-establishment of opinion

Since a search has been carried out only for arrays as specified in the original claims (i.e. containing at least one of sequences 19, 32, 41, 44, 48, 82 and 117 to 135), the following opinion relates only to these arrays.

5. Box V - Novelty (PCT Article 33(2)) and inventive step (PCT Article 33(3))

Arrays containing at least one of sequences 19, 32, 41, 44, 48, 82 and 117 to 135 or having one of these sequences with a maximum of three substitutions are not known from the prior art.

Although claims 1 to 23 are not covered by the present report, it is noted that the primers which they describe are novel over the prior art (DE 100 09 143) and have certain advantages (see Examples 1 to 3). The amplification products obtained using these primers can hybridise onto sequences 19, 32, 41, 44, 48, 82 and 117 to 135. The technical problem addressed is that of providing probes for diagnosing HPV infections. Since the region amplified by the aforementioned primers has advantages in comparison with the prior art, the arrays containing the specified probes can be considered inventive.